PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
72154PC/RO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/SE2004/001124	09.07.2004	09.07.2003
International Patent Classification (IPC) or national classification and IPC		
A61M 5/32, A61M 25/06		
Applicant		
Saldell, Vincent		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))
      _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11.01.2005	04.07.2005
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Hélène Sundström/MP Telephone No. +46 8 782 25 00

Form PCT/IPEA/409 (cover sheet) (April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2004/001124

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

☐ the international application as originally filed/furnished

☒ the description:

pages 1-17 as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☒ the claims:

pages _____ as originally filed/furnished
pages* _____ as amended (together with any statement) under Article 19
pages* 20-23 received by this Authority on 11.01.2005
pages* _____ received by this Authority on _____

☒ the drawings:

pages 1-9 as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to the sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2004/001124

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-20	YES
	Claims		NO
Inventive step (IS)	Claims	1-20	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document cited in the International Search Report:
D1: DE 9216534 U1

The cited document represents the general state of the art.
The invention defined in claims 1- 20 is not disclosed by this document.
The cited prior art does not give any indication that would lead a person skilled in the art to the claimed device for protection of a needle for a medical device. Therefore, the claimed invention is not obvious to a person skilled in the art.
Accordingly, the invention defined in claims 1- 20 is novel and is considered to involve an inventive step. The invention is industrially applicable.

Claims

1. Device for protection of a needle (6) for a medical device (7) that includes a first part (1) and a second part (2), which are movably connected, the first part (1) including a holding means (5) for retaining the medical device (7), so that the two parts (1,2) can be brought together to a first position (13) for enclosing the needle and can be separated from each other to a second position (14) where a retained needle (6) is in a free position (14), **characterised in** that
- the first part is pivotally connected about an axis to the holding means (5),
- the second part is pivotally connected about an axis to the first part at a distance from the holding means,
- said axes are essentially parallel and sufficiently rigid to form a system in which the medical device with the needle only can describe a plane that is perpendicular to the joint axes, whereby the two parts are capable of protecting the user from the tip of the needle in directions facing the user before, during and after the needlestick on the patient, and
- the second part (2) includes a holder means (3) for fixing said second part.

2. Device according to claim 1, c h a r a c t e r i s e d in that at least one of the parts (1,2) in closed position (13) has a recess (10) complementary to the needle.

3. Device according to claim 1 or 2, c h a r a c t e r i s - e d by that the holding means (5) is separate from the first part (1) and fastened to the first part (1) with a (second) joint device (19).

4. Device according to claim 1, 2 or 3, c h a r a c t e r i s e d in that the holding means (5) has a recess for receiving and retaining said needle.

5. Device according to any of claims 1 - 4, c h a r a c t e r i s e d in that the holding means (5) is fitted with a mechanism for retaining the medical device (7), selected from the group consisting of: snap lock device, screw device.

6. Device according to any of claims 1 - 5, c h a r a c t e r i s e d by means (16) to limit an angle (α) between the first part (1) and the second part (2) in the separated position and/or an angle (β) between the first part (1) and the needle (6) in pivoted position.

7. Device according to claim 6, c h a r a c t e r i s e d in that the angle (α) is about 30° - 60°.

8. Device according to claim 6, c h a r a c t e r i s e d in that the angle (β) is about 50° - 80°.

9. Device according to any of claims 1 - 8, c h a r a c t e r i s e d in that one or both parts (1,2) includes at least one recess (8), designed to, by the capillary force, absorb blood and/or an absorbing material.

10. Device according to any of claims 1 - 9, c h a r a c t e r i s e d in that the second part has an end part (4) for application on a patient, provided with a contact surface of a material with large friction or an adhesive material, such as tape.

11. Device according to any of claims 1 - 10, c h a r a c t e r i s e d in that the second part (2) is reinforced with a penetration protection (17), of metal or of tough plastic, for example.

12. Device according to any of claims 1 - 11, c h a r a c t e r i s e d in that the first and second part (1,2) of the device has a locking mechanism in the form of cooperating snap lock elements, Velcro tape or adhesive material, to, in the first position (13), secure the parts to each other.

13. Device according to any of claims 1 - 12, c h a r a c t e r i s e d in that medical device (7) is a vein needle, an injection syringe or an iv cannula with stylet.

14. Device according to any of claims 1 - 13, c h a r a c t e r i s e d in that the joint device (12) is a device selected from the group consisting of: flexible material bridge, pivot pin device.

15. Device according to any of claims 3 - 14, c h a r a c t e r i s e d in that the second joint device (19) is a device selected from the group consisting of: flexible material bridge, pivot pin device.

16. Device according to any of claims 1 - 15, c h a r a c t e r i s e d in that the holder means (3) is a handle (3) for a user.

17. Device according to any of claims 1 - 16, c h a r a c t e r i s e d in that said holder means includes a fixing means (23) that is attachable to the body of a patient.

18. Device according to any of claims 1 - 17, c h a r a c t e r i s e d in that the fixing means (23) is any means selected from the group consisting of: tape, string, strap, ring, fastening flap.

19. Device according to claim 18, c h a r a c t e r i s e d in that at least a section of the fixing means (23) is detachably fastened to the second part (2).

20. Medical unit comprising a medical device (7) with a needle (6), c h a r a c t e r i s e d in that it includes a device according to any of the claims 1 - 19.